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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SMITH, CAROLYN L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/006,601	HOUGAARD, PHILIP	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *03192002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims herein under examination are 1-81.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-19, 24-40, 45-59, 64-66, 70, 74, and 78-81 are rejected under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter. As written, these claims can be interpreted to be computer-related methods that appear to lack any physical result performed outside of a computer.

As stated in MPEP § 2106, (IV)(B)(2)(b), to be statutory, a claimed computer-related process must either: (A) result in a physical transformation outside the computer for which a practical application in the technological arts is either disclosed in the specification or would have been known to a skilled artisan (discussed in MPEP § 2106 (IV)(B)(2)(b)(i)), or (B) be limited to a practical application within the technological arts (discussed in MPEP § 2106 (IV)(B)(2)(b)(ii)).

As stated in MPEP § 2106 (IV)(B)(2)(b)(i), the independent physical acts may be post- or pre-computer processing activity as described below:

> A process is statutory if it requires physical acts to be performed outside the computer independent of and following the steps to be performed by a programmed computer, where those acts involve the manipulation of tangible physical objects and result in the object having a different physical attribute or structure. Diamond v. Diehr, 450 U.S. at 187, 209 USPQ at 8. Thus, if a process claim includes one or more post-computer process steps that result in a physical transformation outside the computer (beyond merely conveying the direct result of the computer operation), the claim is clearly statutory.

> Another statutory process is one that requires the measurements of physical objects or activities to be transformed outside of the computer into computer data (In re Gelnovatch, 595 F.2d 32, 41 n.7, 201 USPQ 136, 145 n.7 (CCPA 1979) (data-gathering step did not measure physical phenomenon); Arrhythmia, 958 F.2d at 1056, 22 USPQ2d at 1036), where the data comprises signals corresponding to physical objects or activities external to the computer system, and where the process causes a physical transformation of the signals which are intangible representations of the physical objects or activities. Schrader, 22 F.3d at 294, 30 USPQ2d at 1459 citing with approval Arrhythmia, 958 F.2d at 1058-59, 22 USPQ2d at 1037-38; Abele, 684 F.2d at 909, 214 USPQ at 688; In re Taner, 681 F.2d 787, 790, 214 USPQ 678, 681 (CCPA 1982).

As stated in MPEP § 2106 (IV)(B)(2)(b)(ii), the computer-related process may be limited to a practical application in the technological arts as described below:

> There is always some form of physical transformation within a computer because a computer acts on signals and transforms them during its operation and changes the state of its components during the execution of a process. Even though such a physical transformation occurs within a computer, such activity is not determinative of whether the process is statutory because such transformation alone does not distinguish a statutory computer process from a nonstatutory computer process. What is determinative is not how the computer performs the process, but what the computer does to achieve a practical application. See Arrhythmia, 958 F.2d at 1057, 22 USPQ2d at 1036.

Claims 1-19, 24-40, 45-59, 64-66, 70, 74, and 78-81 do not fulfill either of these statutory requirements and are therefore rejected under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter.

Claims 1-19, 24-40, 45-59, 64-66, 70, 74, and 78-81 are rejected under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter. As written, the claims appear to be directed to a method that merely manipulates numbers, abstract concepts or ideas, or signals representing any of the foregoing.

As stated in MPEP § 2106, (IV)(B)(1), if the "acts" of a claimed process manipulate only numbers, abstract concepts or ideas, or signals representing any of the foregoing, the acts are not being applied to appropriate subject matter. Schrader, 22 F.3d at 294-95, 30 USPQ2d at 1458-59. Thus, a process consisting solely of mathematical operations, i.e., converting one set of numbers into another set of numbers, does not manipulate appropriate subject matter and thus cannot constitute a statutory process.

In practical terms, claims define nonstatutory processes if they:

> – consist solely of mathematical operations without some claimed practical application (i.e., executing a "mathematical algorithm"); or
> – simply manipulate abstract ideas, e.g., a bid (Schrader, 22 F.3d at 293-94, 30 USPQ2d at 1458-59) or a bubble hierarchy (Warmerdam, 33 F.3d at 1360, 31 USPQ2d at 1759), without some claimed practical application.

Claims 1-19, 24-40, 45-59, 64-66, 70, 74, and 78-81 do not fulfill any of these statutory requirements and are therefore rejected under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter.

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claims 1 (line 10), 24 (line 9), and 45 (line 9) recite the limitation "the expected degradation rate". There is insufficient antecedent basis for this limitation in the claim. Claims 2-23, 25-44, and 46-81 are also rejected due to their dependency from claims 1, 24, and 45.

Claims 1 (line 12), 24 (line 11), and 45 (line 11) recite the limitation "the intermediate position". There is insufficient antecedent basis for this limitation in the claim. Claims 2-23, 25-44, and 46-81 are also rejected due to their dependency from claims 1, 24, and 45.

Regarding claims 20, 41, and 60, the phrase "such as" renders these claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Claims 21-23, 42-44, and 61-63 are also rejected due to their dependency from claims 20, 41, and 60.

The preamble of claim 45 is directed to a method for planning a stability study whereas one of the limitations in the body of the claim is directed to conducting a stability study. Therefore, it is unclear if the preamble or the body of the claim is intended to control the metes and bounds of claim 45. Claims 46-63, 74-77, and 80-81 are also rejected due to their direct or indirect dependency from claim 45.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 10, 20-23, and 64-69 are rejected under 35 U.S.C. 102(e)(1) as being anticipated by Levinson et al. (US 2002/0177167).

Levinson et al. disclose a method for planning, performing, and assessing results of pharmaceutical compositions including stability properties (abstract, paragraphs 0016 and 0067). Levinson et al. disclose selecting a plurality of combinations of values of experimental parameters, including amount of dissolved component (release limit variable) (abstract, paragraphs 0070-0074). Levinson et al. disclose a system delivering nanoliter samples for hybridization analysis (paragraphs 0077 and 0080) which represents a selected value for release limit variable for a given specification test. Levinson et al. disclose shelf-life and bioavailability may vary due to chemical interactions, excipients used, and administration use (paragraph 0004). Levinson et al. disclose incubating samples for various lengths of time (shelf-life) such as 5 minutes, 60 minutes, 48 hours, etc. to monitor experiments as a function of time as well as the "ageing process" (paragraph 0086) which represents selecting a desired length of shelf-life, selecting a time at which analysis is performed, and selecting time points for measurements.

Levinson et al. disclose selecting various time controlled points because the stability of the first solid-form may not be as stable as other forms over a period of time (paragraph 0086) such that measurements taking of a composition during an middle time point (i.e. 60 minutes as mentioned above) represents selecting a value for the intermediate precision of the measurement. This analysis also represents an interim analysis, as stated in instant claims 64 and 65. Levinson et al. disclose selecting distinct combinations of experimental parameters to be measured during the experiment (paragraph 0014) which represents selecting a number of measurements of predetermined test variables. Levinson et al. disclose estimating a property in a chemical composition, generating a predictive model based on experimental result sets according to the property, and the possible formulation changes from an original solid form at different time points of an expected range (paragraph 0016) which represents selecting a value for the expected degradation rate. Levinson et al. disclose preparing samples and then reversing formation of solid-forms (paragraph 0039) which represents degradation. Levinson et al. disclose dissolution rates (0036) which represents degradation rates. The Merriam-Webster online dictionary defines dissolution as a dissolving or breakdown of an assembly which represents degradation. Levinson et al. disclose integrating information to maximize the probability of yielding compositions that possess a desired property over an expected range of conditions of manufacture (packaging), storage (shelf-life), and administrations (paragraph 0012) which represents selecting a probability level regarding a level of certainty of the outcome of the study. Levinson et al. disclose collecting data and associating data from previously run experiments (paragraph 0020) which represents basing values on previous long-term studies (note that "long-term" is a broad term that can therefore be any timeframe greater than 0 seconds), as stated in instant claim 2.

Levinson et al. disclose processing, followed by selecting a set of experimental parameter values and compositions having optimized properties (paragraph 0099) which represents optimizing variables by changing one or more variables from multiple experiments. Levinson et al. disclose using thousands of experimental formulations (paragraph 0095) which represents alternate formulations, as stated in instant claim 10. Levinson et al. disclose the solid-forms and pharmaceuticals which is any substance administered to humans such as prescription pharmaceuticals and over the counter pharmaceuticals (paragraphs 0040 and 0041) which represents administering of a pharmaceutical formulation such as a tablet, as stated in instant claim 20. Levinson et al. disclose variations in the solid forms manufacturing (packaging) (paragraph 0008), structural property such as size (paragraph 0069), as well as formulas and concentrations (dosages) (paragraph 0095), as stated in instant claims 21, 22, and 23. Levinson et al. disclose selecting thousands of experimental formulations with three excipients (Merriam-Webster online dictionary defines as an inert substance used as a drug vehicle) and one or more active agents with experimental iterations being performed (paragraphs 0101, 0102, 0105, 0107, and 0108), which represents at least three batches of pharmaceutical compositions as stated in instant claims 66-69.

Thus, Levinson et al. anticipate the limitations in claims 1-2, 10, 20-23, and 64-69.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located

in Crystal Mall 1. The faxing of such papers must conform to the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

June 16, 2004

Ardin H. Marschel 6/22/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER